K130714

510(K) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR 807.92 and the requirements of the Safe Medical Device ACT (SMDA) of 1990.

1. Sponsor Name

Submitter's Name:	Radius Medical, LLC
Address:	577 Main St, Suite 360 Hudson, MA 01749
Phone:	(978) 263-4466
Fax:	(978) 263-4465
Contact Person:	Richard DeMello
Date of Preparation:	March 7, 2013

AUG 2 2 2013

2. Device Information

Trade Name:	Prodigy Support Catheter
Common Name:	Percutaneous catheter
Class:	II
Classification Name:	Percutaneous catheter (21 CFR 870.1250, Product Code DQY)

3. Predicate Devices

Minnie™ Support Catheter (K082337) manufactured by Vascular Solutions, Inc.

Maverick XL PTCA Catheter (P860019/183) manufactured by Boston Scientific.

NC Quantum Apex OTW PTCA Dilatation Catheter (P860019/241) manufactured by Boston Scientific.

4. Device Description

The Prodigy Support Catheter is an over-the-wire (OTW) 2-lumen catheter with a 5 mm elastomeric balloon located near the distal tip. One lumen of the catheter is used to inflate and deflate the balloon with contrast fluid. The second lumen provides access for a guidewire. Two side legs are located at the proximal catheter

end to provide access to the balloon lumen and the guidewire lumen. A pressure relief valve is attached at the proximal end of the balloon side leg and allows for connection with an inflation device. There are two radiopaque marker bands located at each end of the balloon. The inflated balloon diameter is variable with increased pressure up to 5 mm.

The Prodigy Support Catheter is packaged in a mylar/Tyvek pouch and ETO sterilized to SAL 10^{-6}.

5. Intended Use

The Prodigy Support Catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the arterial and or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices.

6. Comparison of Technological Characteristics

The **Prodigy Support Catheter** is similar in materials, function and design to predicate NC Quantum Apex OTW PTCA Dilatation Catheter (P860019/241) and the Maverick XL PTCA Catheter (P860019/183). All devices have two-lumen polymer shafts with a polymer balloon located near the tip of the catheter. One lumen of the shaft allows for inflation of the balloon with contrast medium while the other lumen permits the guidewire to facilitate advancement of the catheter. The balloon sizes on the predicate devices range from 1.5 mm to 6 mm while the balloon on the Prodigy Support Catheter expands up to 6 mm. The Prodigy and NC Quantum Apex catheters both include side leg adaptors to provide separate access to the balloon inflation lumen and the guidewire lumen. All catheters include two radiopaque marker bands at either end of the balloon to aid in positioning the balloon within the patient. The NC Quantum Apex OTW and Maverick XL catheters are used for dilating a stenotic portion of a coronary artery. The Prodigy Support Catheter is for accessing discrete regions of the arterial and or coronary vasculature and to facilitate placement and exchange of guidewires and other interventional devices. All are introduced into the body through a guidecatheter or outer sheath and are directed through the artery over a guidewire. All devices have a balloon that is inflated at the distal end of the catheter into contact with the vessel wall. The NC Quantum Apex and Maverick balloon is used to dilate a narrowing in an artery using high pressures. The Prodigy balloon is used to anchor the catheter within the artery using low pressures. Guidewires can be placed and exchanged through the Prodigy and NC Quantum Apex OTW catheters.

The design and function of the **Prodigy Support Catheter** is similar to the Minnie™ Support Catheter (K082337). Both devices utilize a polymer shaft, are introduced into the body through a guidecatheter or outer sheath and are directed through the artery over a guidewire. Both catheters provide support for guidewires during interventional procedures and allow for exchanging of guidewires and other interventional devices. The Minnie catheter has a single lumen that accepts a guidewire. The Prodigy catheter has two lumens, one for a guidewire and one to inflate the distal balloon. Both catheters have radiopaque markers at the distal end to aid in location of the catheter tip.

7. Performance Data

Biocompatibility Testing

Biocompatibility tests were conducted on the **Prodigy Support Catheter** according to the requirements of *Guidance for Industry and FDA Staff-Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 20102010* and ISO10993-1:2009, *Biological Evaluation of Medial Devices Part-1: Evaluation and Testing.* The following test were conducted:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemolysis
- Material Mediated Pyrogenicity
- Thombogenicity
- Complement Activation

In Vitro Performance Testing

In vitro performance tests were performed on the **Prodigy Support Catheter** according to the requirements of *Guidance for Industry and FDA Staff-Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010. In-vitro* performance testing conducted on the Prodigy Support Catheter included:

- Dimensional Verification
- Balloon Preparation, Deployment and Retraction
- Balloon Burst Pressure
- Balloon Fatigue

- Balloon Inflation/Deflation Time
- Catheter Bond Strength
- Flexibility and Kink Test
- Torque Strength
- Radiopacity
- Balloon Holding Force

Conclusion

Based upon these biocompatibility and *in vitro* performance tests, the Prodigy Support Catheter has been shown to be substantially equivalent to the currently marketed Minnie Support Catheter, Maverick XL PTCA Catheter and NC Quantum Apex OTW PTCA Dilatation Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Radius Medical, LLC
c/o Mr. Richard DeMello
Vice President
577 Main St, Suite 360
Hudson, MA 01749

Re: K130714
Trade/Device Name: Prodigy Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 12, 2013
Received: July 18, 2013

Dear Mr. DeMello:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130714

Device Name: Prodigy Support Catheter

Indications For Use:

The Prodigy Support Catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the arterial and or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)